

# TLC Trial Form V1 REVIEW.04

## Review of Eligibility Lab Results

### Pre-Randomization Visit 1

|                |                             |
|----------------|-----------------------------|
| Center ID:     | _____ - _____               |
| Screening ID:  | S _____ - _____             |
| Visit Code:    | V 1                         |
| Date labs done | ____ / ____ / ____ mm/dd/yy |

**INSTRUCTIONS:** This form is to be completed as lab results from Pre-Randomization Visit 1 become available.

#### LOCAL LABORATORY RESULTS

1. Hemoglobin \_\_\_\_\_ . \_\_\_\_\_
2. Red cell distribution width \_\_\_\_\_ . \_\_\_\_\_
3. MCV \_\_\_\_\_ . \_\_\_\_\_
4. Platelet count \_\_\_\_\_ K
5. Absolute neutrophil count \_\_\_\_\_ , \_\_\_\_\_
6. Alkaline phosphatase \_\_\_\_\_
7. AST \_\_\_\_\_
8. ALT \_\_\_\_\_
9. Serum creatinine \_\_\_\_\_ . \_\_\_\_\_

#### EVALUATION OF ELIGIBILITY BASED ON LOCAL LAB RESULTS

10. Is the hemoglobin less than 9.0?  
 No                       Yes
11. Is the serum creatinine greater than 1.0?  
 No                       Yes

*If you have answered Yes to any of the above questions, this child is **NOT ELIGIBLE** for the TLC Trial.*

12. Is the hemoglobin greater than or equal to 9.0 but less than 10.0 **AND** is the RDW increased?  
 No                       Yes
13. Is the platelet count less than 150,000/mm<sup>3</sup>?  
 No                       Yes
14. Is the absolute neutrophil count less than 800/mm<sup>3</sup>?  
 No                       Yes
15. Is the alkaline phosphatase greater than twice the upper limit of normal for your lab?  
 No                       Yes
16. Is the AST greater than twice the upper limit of normal for your lab?  
 No                       Yes

Send to:  
TLC Data Coordinating Center

Center ID: \_\_\_\_\_ - \_\_\_\_\_  
 Screening ID: S \_\_\_\_\_ - \_\_\_\_\_  
 Visit Code: \_\_\_\_\_ V 1  
 Date labs done \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy

17. Is the ALT greater than twice the upper limit of normal for your lab?

( )<sub>0</sub> No ( )<sub>1</sub> Yes

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*If you have answered Yes to any of the above questions, this child's enrollment must be **DEFERRED** pending resolution of abnormalities.*

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### CDC LAB RESULTS

18. CDC PbB \_\_\_\_\_

19. Is the CDC PbB less than 20 µg/dL or greater than 44 µg/dL?

( )<sub>0</sub> No ( )<sub>1</sub> Yes

20. CDC Ferritin \_\_\_\_\_ ( )<sub>1</sub> not available

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*If the CDC PbB is less than 20 or greater than 44 µg/dL, this child is **NOT ELIGIBLE** for the TLC Trial.*

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### ADMINISTRATIVE MATTERS

21. Date form completed \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy

22. TLC Staff \_\_\_\_\_ - \_\_\_\_\_  
Signature TLC Code

23. Eligibility status ( )<sub>1</sub> Eligible ( )<sub>2</sub> Not eligible, specify \_\_\_\_\_  
 ( )<sub>3</sub> Defer, specify \_\_\_\_\_

*If deferred:*

24. Date of V1A \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ mm/dd/yy Time \_\_\_\_\_ : \_\_\_\_\_

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### COMMENTS